K111288

Lake Region Medical

PRODUCT: ANCHORWIRE™ GUIDEWIRES
SUBMISSION DATE: August 1, 2011
SUBMISSION TYPE: TRADITIONAL

AUG - 2 2011

SECTION 5.0: 510(k) SUMMARY

5.1 MANUFACTURER / REGISTRATION INFORMATION

Lake Region Medical
340 Lake Hazeltine Drive
Chaska, MN 55318-1029 USA
FDA REGISTRATION NUMBER: 2126666

Contact Person: Mathew Pexa
Title: Regulatory Specialist I
Telephone: (952) 641-8511
Fax: (952) 448-3441

5.2 TRADE NAME (PROPRIETATY NAME)

Anchorwire™ Guidewire

Lake Region Medical (LRM) produces Guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors.

5.3 DEVICE COMMON NAMES/USUAL NAMES/CLASSIFICATION NAMES

These devices are commonly known as Guides, Guidewires, or spring Guidewires. The current classification name and product code is Wire, Guide, Catheter (DQX) and regulation number 870.1330.

5.4 CLASS OF DEVICE

This type of Guidewire was originally listed as a Class II device by the Cardiovascular (DQX) Review Panel.

5.5 IDENTIFICATION OF PREDICATE DEVICE(s)

510(k) NUMBER	MANUFACTURER	DEVICE NAME
K042370	Toray Industries (America), Inc	Torayguide®

5.6 DEVICE DESCRIPTION

The Lake Region Anchorwire™ guidewires are comprised of a stainless steel core wire with a flexible, spiral shaped stainless steel coil on the distal end. The guidewire is offered in several lengths including 175cm, 203cm, and 230cm. The product is supplied sterile for single use only.

MAX OD: .025"

LENGTHS: 175cm - 230 cm

TIPS: Spiral

5.7 TECHNOLOGICAL CHARACTERSTICS

The primary modifications between the Toray Industries (America), Inc. Torayguide® and the Lake Region Anchorwire™ is the intended use statement, shorter taper length, joining method of distal tip and dimension of the spiral diameter. The table below shows the technological differences between the proposed Anchorwire™ and predicate Torayguide® guidewires.

PREDICATE DEVICE - TORAYGUIDE®	PROPOSED DEVICE - ANCHORWIRE™
SPIRAL DIAMETER	
39-45mm	36-46mm
DISTAL TIP JOINING METHOD	
Solder	Weld
TAPER LENGTH	
29cm	26cm

5.8 COMPLIANCE WITH APPLICABLE STANDARDS

The Lake Region Anchorwire™ is in compliance with ISO 10993, ISO 11135, ISO 11070, ISO 15223, EN 980 and ISO 594.

SECTION 5.0: 510(k) SUMMARY

5.9 INTENDED USE STATEMENT

The ANCHORWIRE™ guidewires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

5.10 COMPARISON

The Anchorwire™ Guidewires are substantially equivalent to the Torayguide® Guidewires (K042370).

5.11 QUALIFICATION TESTING

The conclusions drawn from nonclinical, biocompatibility and GLP animal study demonstrate the device is as safe, as effective, and performs at least as safely and effectively as the legally marketed device.

NON-CLINICAL TESTS

In order to demonstrate equivalence of the Anchorwire™ guidewire, LRM performed testing to established requirements. Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes. A list of applicable non-clinical tests included performed at baseline and aging include:

- Dimensional
- Kink Resistance
- Device Compatibility
- Pull Strength
- Pouch Peel
- Spiral Compression
- Dye Penetration
- Visual
- Radiopacity
- Fracture
- Flex
- Corrosion
- Strength of Union
- Body Stiffness
- Particulate
- Spiral Memory
- Coil Free Play

BIOCOMPATIBILITY TESTING

Biocompatibility testing per ISO 10993 series has been performed on the Anchorwire™ devices and has been found to be acceptable.

- Cytotoxicity
- Kligman Maximization Test
- Systemic Toxicity
- Rabbit Pyrogen
- Hemolysis
- Complement Activation Assay
- Thrombogenicity
- Lee & White Coagulation
- Unactivated Thromboplastin Time Assay
- USP Physicochemical Test
- Inhibition and Enhancement

GLP ANIMAL STUDY

An animal study was completed evaluating the clinical safety and performance of the Anchorwire™ to the currently marketed device. The study proved the Anchorwire™ is as safe as effective and performs at least as safely and effectively as the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lake Regional Medical
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

AUG - 2 2011

Re: K111288
Device Name: Anchorwire Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II (two)
Product Code: DQX
Dated: July 20, 2011
Received: July 21, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K111288

DEVICE NAME: *ANCHORWIRE™ Guidewires*

INDICATIONS FOR USE:

The ANCHORWIRE™ guidewires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

PRESCRIPTION USE X *AND/OR* **OVER-THE-COUNTER USE** _____
(Part 21 CFR 801 Subpart D) *(21 CFR 807 Subpart C)*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111288